UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,114	11/14/2005	F. C. Thomas Allnutt	08717.0009	9387

22852 7590 02/04/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
02/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,114	ALLNUTT ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-48* is/are pending in the application.

4a) Of the above claim(s) *41-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-40 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/23/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received November 19, 2007.

Election/Restrictions

Applicant's election with traverse of group VII, claims 34-40 and 48 is acknowledged. Applicants traverse the restriction requirement between groups VI and VII. Upon further consideration the restriction requirement between groups V, VI, and VII is withdrawn. Claims 27-40 and 48 are under examination. Claims 41-47 are withdrawn because the claims are drawn to the non-elected invention.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 23, 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Claim Objections

Claims 33 and 40 are objected under 37 CFR 1.75(c) as being in improper form because multiple dependent claim 33 depends from claims 27-32, and multiple dependent claim 40 depends from claims 34-39. See MPEP 607.1 "One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such other claims in the alternative only."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 34-40 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 34-40 and 48 recite: "A genetic construct comprising at least one viral coat protein containing exogenous sequence for displayed peptides or proteins." It is noted that a genetic construct would typically encode a protein, as opposed to comprising a protein. The recitation of a genetic construct is interpreted to mean DNA. While a DNA can encode a protein, the DNA does not typically comprise a protein. Clarification and correction is required.

Claim 31 recites the limitation "the complex". There is insufficient antecedent basis for this limitation in claim 27.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make, and/or use the invention.

The claim is drawn to a vaccine comprising the recombinant virus-like particle. The claim is rejected because the present specification does not provide sufficient enablement for the claimed vaccines.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, the factors deemed relevant are those of the amount of direction and the working examples provided, that quantity of experimentation necessary, the (un)predictability of the art, and the breadth of the claims.

The claim is broadly drawn to any vaccine. The specification does not sufficiently support the claimed vaccines. The specification discloses/contemplates that the virus like particles of the present invention would express immunostimulating antigens for the diseases to which the vaccine is targeted such as HIV (Examples 1-5). The working examples in the specification provide methods of making the VLPs. However the working examples do not provide sufficient evidence with regard to the claimed vaccines. The working examples do not show that an infection with an HI or any other pathogen can be prevented using the VLPs of the present invention. The term "vaccine" by definition implies any preparation intended for active

immunological prophylaxis; e.g., preparations of killed microbes of virulent strains or living microbes of attenuated (variant or mutant) strains; or microbial, fungal, plant, protozoal, or metazoan derivatives or products. Although just about any protein when inoculated can cause an immune reaction, the prophylactic nature of this reaction is not guaranteed and has to be experimentally determined. Prophylaxis is defined as the prevention of disease or of a process that can lead to disease. This is achieved by use of an antigenic (immunogenic) agent to actively stimulate the immunological mechanism, or the administration of chemicals or drugs to members of a community to reduce the number of carriers of a disease and to prevent others contracting the disease.

The obstacles to developing a successful therapy of HIV are well documented in the literature. These obstacles include 1) the extensive genomic diversity and mutation rate associated with the HIV retrovirus, particularly with the respect to the gene encoding the envelope protein. 2) The fact that the mode of viral transmission includes both virus-infected mononuclear cells, which pass the infecting virus to other cells in a covert manner, as well as via free virus transmission. 3) The establishment of a latent viral infection. 4) The ability of the virus to evade the immune responses in the central nervous system due to the blood-brain barrier. 5) The complexity and variation of the pathology of HIV infection in different individuals. 6) The inability of a natural infection to one strain of HIV to protect an individual from being infected with another strain of HIV (Machuca et al. Intervirology 1999, Vol. 42, p. 37-42, see discussion). These obstacles establish that the contemporary knowledge in the art would not allow one of skill in the art to use the claimed vaccine to treat and/or prevent HIV infection without undue experimentation. Applicants have not provided any convincing evidence that their claimed

vaccine is indeed useful as a therapeutic or preventative for HIV or any other infection and have not provided sufficient guidance in to allow one skilled in the art to practice the claimed invention without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 28, 30-37, 38, 40 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Chapman et al. (US. Patent 6,232,099 B1).

Claims are drawn to a recombinant virus-like particle comprising at least one viral coat protein containing exogenous sequence for displayed peptides or proteins and the methods of producing a recombinant virus-like particle (VLP). The second exogenous sequence of the VLP functions to target the particle to a specific location. Claims are drawn to a vaccine comprising the recombinant virus like particle. It is noted that the intended use of the virus like particles as a vaccine is not limiting, however Chapman does disclose the use of his virus like particles as vaccines as discussed below.

Chapman discloses recombinant virus like particles comprising viral coat protein fused with foreign/exogenous proteins (see claim 49, column 6, lines 5-44, Examples 2 and 3). Chapman discloses vaccines comprising the VLPs (see column 6, line 43). Chapman discloses virus like particles comprising second exogenous sequence which function is to target the VLP to

the specific location (see claims 1, 19, 25, 29, and 33). It is noted that Chapman refers to the targeting sequence as a target moiety. The exogenous sequence of Chapman's VLP construct is inserted into a region unnecessary for VLP assembly, because the exogenous sequence is inserted into the viral coat protein and the Chapman's VLP does assemble. Chapman disclose methods for producing recombinant virus like particles comprising providing a viral genome, isolating viral coat protein sequence, inserting at least one exogenous sequence and at least one second exogenous sequence encoding a targeting sequence/ target moiety, cloning the viral coat protein sequence and transforming an appropriate host (see claims 1-49 and Examples 1-3).

Thus by this disclosure Chapman anticipate the present claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. (US. Patent 6,232,099 B1) as applied to claims 27 and 34 and further in view of Harris et al. (International Immunology, 1997, Vol. 9, p. 273-280).

Chapman teaches the VLPs of the present invention as discussed above. Chapman does not teach the exogenous protein peptide being an allergen.

Harris teaches virus like particles expressing peptide epitopes of the major house dust mite allergen Der p1 (see the entire document).

It would have been obvious to make a VLP expressing a protein or peptide that is an allergen in an animal.

One would have been motivated to express Harris's major house dust mite allergen Der p1 in the viral coat protein of Chapman's VLP, because Chapman teaches that an antigenic epitope of interest can be expressed in his VLPs (see claims 12 and 38), and because Harris teaches that VLPs serve as a strong antigen presentation system known to induce strong cell mediated immune responses and because Harris was able to in vivo prime the Th1 cells with the house dust mite antigens by administering house dust mite antigen expressing VLPs in mice (see Figures 1-4 and Discussion).

One would have had a reasonable expectation of success to provide VLPs expressing allergenic epitope peptides because the recombinant virus technology used for making such recombinant VLPs has been well established in the art as evidenced by Chapman and Harris.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ABoesen

Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 1-31-2008
Primary Examiner, TC1600